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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,692

09/21/2006

Jun Hirabayashi

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KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

NOTIFICATION DATE

DELIVERY MODE

09/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

tanya.harding@klarquist.com
docketing@klarquist.com

Office Action Summary	Application No. 10/596,692	Applicant(s) HIRABAYASHI ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11-15, 17 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11-15, 17 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2010 has been entered.

Status of the Claims

2. Claims 4-10, 16, 18-28 have been canceled.
3. Claims 29-32 have been added.
4. Claims 1-3, 11-15, 17 and 29-32 are pending.

Information Disclosure Statement

5. The information disclosure statement filed 8/18/2010 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Array Pro Analyzer Product Description lacks a date including the year of publication.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 11-13 and 29-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8 of copending Application No. 10/596,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a method for analyzing an

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interaction between a sugar chain and a protein comprising the use of fluorescent-labeled sugar chain.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. Claim 1-3, 11-13 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al (US 2002/0192690) in view of Hirabayashi et al (Journal of Chromatography A. Vol. 890:261-271. 2000) and Mir (US 2004/0248144).

Chan discloses a biosensor comprising a substrate having one or more probes which bind to a target molecular coupled to a semiconductor. The probes each include one or more semiconductor-binding groups which enable them to coupled to the semiconductor structure (either directly via a coupling agent), and one or more target binding groups that bind to a target molecule. See paragraph [0040] and paragraphs [0062] – [0063]. Chan teaches that biosensors typically consist of two components: a highly specific recognition element and a transducing structure that converts the molecular recognition event into a quantifiable signal. Biosensors can detect a variety of biomolecular complexes including oligonucleotide pairs, antigen-antibody pair, hormone-receptor, enzyme-substrate and lectin-glycoprotein interactions. Signal transductions are generally done with electrochemical, fluorescence or optical absorption, etc. See paragraph [0005]. Chan teaches coupling agents including silanes functionalized with an epoxide group, a thiol, or an alkynyl and halide containing compounds. See paragraph [0049]. With respect to silane compounds, Chan teaches 3-glycidoxypropyl trimethoxysilane (GTMS).

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See paragraph [0050] and [0104]. Chan teaches lectin-glycoprotein, antibody—antigen interaction, etc. see paragraph [0005]. Chan also teaches method for using the same. See paragraph [0012] and claims 35-38. Chan teaches the use of fluorescence labels. See paragraph [0090].

Chan differs from the instant claims in failing to specifically teach fluorescently labeled sugar chain or glycoconjugate. Chan also fail to specifically teach digitizing and quantifying the fluorescence intensity.

Hirabayashi discloses an affinity chromatography method for quantitative analysis of biomolecular interactions such as enzyme-substrate, lectin-oligosaccharides, etc. Hirabayashi teaches that fluorescence-based detection raises the sensitivity of the method and specifically teaches fluorescent sugars (pyridylaminated oligosaccharides; 320nm and 400nm for excitation and emission, respectively), or lectin proteins were used as analytes. See page 262, first full paragraph.

And Mir discloses evanescent wave excitation for detecting binding events in biosensors. See paragraphs [0040] and [0203]. Mir teaches the use of computer and software for scanning and processing of biosensor. Signals can be processed from the CCD or other imaging device and stored digitally for subsequent data processing. See paragraphs [0221], [0225] and [0230]. Mir also teaches that single fluorophores have quantized emission and can be distinguished from background noise. See paragraph [0237]. Mir also teaches digital analysis of signals and specifically teaches bulk analysis of the signal in analogue by an intensity value, from which a concentration may be inferred, and this indicates the result of the assay in terms of a base call or it may indicate the level of a particular molecule in the sample. See paragraph [0246]. Mir also

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teaches comparing the result with a standard to determine the identity of the analytes. See paragraph [0316] and [0444]. Mir also teaches a homogenous method of detecting analytes. See paragraph [0404].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the binding event taught by Chan using evanescent wave excitation because Mir teaches that such technique is conventional and well known in the art. A skilled artisan would have had a reasonable expectation of success in using the digitizing and quantifying method taught by Mir to detect the fluorescently labeled glycoproteins in the method of Chan because Hirabayashi teaches that fluorescence-based detection raises the sensitivities of the affinity method.

8. Claims 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan in view of Hirabayashi et al (Journal of Chromatography A. Vol. 890:261-271. 2000) and further in view of Brennan et al (US 2003/0232382).

See the discussion of Chan and Hirabayashi above. These references differ from the instant claims in failing to teach the use of rubber to define individual reaction vessels.

Brennan, however, teaches means for separating reactants of one reaction from those of another and to prevent reactants of one reaction from entering another reaction before, during, or after assembly. These methods may include mechanical methods, chemical methods, or combinations thereof. For example, large numbers of reaction wells may be microfabricated on the surface of a solid support with each well providing a reaction site (FIG. 2). In some embodiments, a liquid polymer (such as Self-Seal®, nail polish, rubber cement, etc.) may be

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employed as a seal between two arrays or between individual reactions to prevent excess solvent evaporation. Selected areas of a solid support surface may also be chemically or photolytically treated before, during or after assembly to provide separation of reactions. See paragraph [0134].

Even though Brennan does not specifically teach that a rubber having one or more holes is applied onto the glass to define the reaction well, the biosensor of Chan as modified by Brennan results in a device where a layer of rubber material is attached to a glass substrate to define individual reaction wells. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Chan as taught by Brennan because Brennan teaches that it is well known in the art to use materials such as rubber to separate reactants of one reaction area from those of another area. The substrate of claim 14 is obvious over Chan, Hirabayashi and Brennan because the references teach a product that is the same as, or an obvious variant of, the product set forth in this product-by-process claim although it is produced by a different process.

Response to Arguments

9. Applicant's arguments with respect to claim 18 August 2010 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
September 7, 2010